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|-------------------------------|-------------------|-------------------|--|
| <b>Notice of Allowability</b> | Application No.   | Applicant(s)      |  |
|                               | 10/802,381        | CARRUTHERS ET AL. |  |
|                               | Examiner          | Art Unit          |  |
|                               | Jeffrey E. Russel | 1654              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the communications filed May 4, 2005 and June 2, 2005.
2. ☒ The allowed claim(s) is/are 1-6, 8-20, 22, 24 and 26-30.
3. ☒ The drawings filed on 17 March 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

1. The amendment after final rejection filed May 4, 2005 has been entered.
2. The appropriate maintenance fees for U.S. Patent No. 6,358,917 have been paid, and therefore the reissue procedures are available for this patent.
3. The consent of assignee to the reissue and the offer to surrender have been received on March 17, 2004.

Note that in view of changes to the reissue rules, actual surrender of the original patent, or submission of a statement as to loss or inaccessibility of the original patent, is no longer required. See 37 CFR 1.178(a).

4. The reissue declaration under 37 CFR 1.175 filed March 17, 2004 and the supplemental reissue declaration under 37 CFR 1.175(b)(1) filed June 2, 2005 are approved.
5. The following is an examiner's statement of reasons for allowance: Claims 1-6, 8-20, 22, 24, and 26-30 are deemed to be allowable over the prior art of record or any combination thereof. The prior art of record does not teach or suggest alleviating downturn of corners of a patient's mouth by injecting Botulinum toxin into depressor anguli oris muscles at each corner of the mouth. The closest prior art of record is deemed to be the Bikhazi et al article (Otol. Head Neck Surg., Vol. 117, pages 303-307). However, the Bikhazi et al article, while teaching the administration of Botulinum toxin into the lower face, does not teach or suggest such injections to alleviate downturn of corners of a patient's mouth. Further, because the Bikhazi et al article intends to improve facial symmetry, the injections themselves are asymmetric, and thus there is no suggestion in the Bikhazi et al article to inject the toxin into a DAO muscle at each corner of

Art Unit: 1654

the mouth. Note also that neither the Carruthers article (57th Annual Meeting American Academy of Dermatology, pages 21-22) nor the Sabbaugh article (Eye World, Vol. 3, pages 37-38) teach treating sad mouth by injecting botulinum toxin into each depressor anguli oris muscle, and thus do not teach or suggest the combination treatment set forth in instant claim 15.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

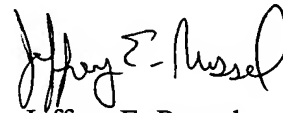
6. As pointed out by Applicants, section 3 of the final Office action incorrectly refers to U.S. Patent No. 5,583,114 as a result of a word processing error. The correct patent number should have been U.S. Patent No. 6,358,917, upon which reissue has been sought in this application.

7. The reference cited in the attached Notice Of References Cited PTO-892, was originally cited during the prosecution of application serial no. 09/382,002, which issued as U.S. Patent No. 6,358,917, upon which reissue has been sought in this application. The reference is cited so that all references cited during prosecution of the parent application are of record in this reissue application.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

June 7, 2005



US006358917B1

**(12) United States Patent**  
**Carruthers et al.****(10) Patent No.: US 6,358,917 B1****(45) Date of Patent: \*Mar. 19, 2002****(54) COSMETIC USE OF BOTULINUM TOXIN FOR TREATMENT OF DOWNTURNED MOUTH****(76) Inventors:** Jean D. A. Carruthers, 943 West Broadway Suite 720, Vancouver, B.C. (CA), V5Z 4E1; Alastair Carruthers, 835 West 10<sup>th</sup> Avenue, Vancouver, B.C. (CA), V5Z 4E8**(\*) Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

**(21) Appl. No.: 09/382,002****(22) Filed:** Aug. 24, 1999**(51) Int. Cl.<sup>7</sup>** ..... A61K 38/16; A61M 31/00**(52) U.S. Cl.** ..... 514/2; 514/844; 514/906; 604/511; 604/522**(58) Field of Search** ..... 128/898; 424/239.1, 424/401; 514/2, 8, 12, 21, 844, 906; 530/350, 395, 825; 604/506, 511, 522**(56) References Cited****U.S. PATENT DOCUMENTS**

✓ 5,401,243 A • 3/1995 Borodic ..... 604/51

**OTHER PUBLICATIONS**✓ Bikhazi et al. Refinement in the Rehabilitation of the Paralyzed Face . . . *Otol. Head Neck Surg.* vol. 117, No. 4, pp. 303-307, Oct. 1997.\*✓ Garcia et al. Cosmetic Denervation of the Muscles . . . *Dermatol. Surg.* vol. 22, pp. 39-43, 1996.\*✓ Guyuron et al. Aesthetic Indications for Botulinum . . . *Plast. Reconstr. Surg.* vol. 93, No. 5, pp. 913-918, Apr. 1994.\*✓ Song. Botulinum Toxin Type A Injection . . . *Annals Pharmacotherapy* vol. 32, pp. 1365-1367, Dec. 1998.\*✓ Wieder et al. Understanding Botulinum Toxin. *Dermatol. Surg.* vol. 24, pp. 1172-1174, 1998.\*✓ Armstrong et al. (1996). "Treatment of facial synkinesis and facial asymmetry with botulinum toxin type A following facial nerve palsy" *Clin. Otolaryngol.*, vol. 21: 15-20.✓ Brandt et al. (1998). "Cosmetic Use of Botulinum A exotoxin for the Aging Neck" *Dermatol. Surg.*, vol. 24: 1232-1234.✓ Carruthers, (1999). "Botulinum Toxin for Midfacial Defects" 57<sup>th</sup> Annual Meeting American Academy of Dermatology, pp. 21-22.✓ Carruthers et al. (1998). "The Adjunctive Usage of Botulinum Toxin" *Dermatol. Surg.*, vol. 24: 1244-1247.✓ Carruthers et al. (1998). "Clinical Indications and Injection Technique for the Cosmetic Use of Botulinum A Exotoxin" *Dermatol. Surg.*, vol. 24: 1189-1194.✓ Carruthers et al. (1998). "History of the Cosmetic Use of Botulinum A Exotoxin" *Dermatol. Surg.*, vol. 24: 1168-1170.✓ Carruthers et al. (1996). "Botulinum A exotoxin in clinical ophthalmology" *Can. J. Ophthalmol.*, vol. 31(7): 389-400.✓ Carruthers et al. (1994). "Botulinum Toxin in the Treatment of Glabellar Frown Lines and Other Facial Wrinkles" in *Therapy with Botulinum Toxin* (Jankovic et al. eds.) Ch. 46: 577-595.✓ Klein (1999). "Botulinum Toxin for the Aging Face" 57<sup>th</sup> Annual Meeting American Academy of Dermatology, pp. 20-20C.✓ Hoefflin (1998). "Anatomy of the Platysma and Lip Depressor Muscles" *Dermatol. Surg.*, vol. 24: 1225-1231.

\* cited by examiner

**Primary Examiner**—Jeffrey E. Russel**(74) Attorney, Agent, or Firm**—Bret E. Field; Bozicevic, Field & Francis**(57) ABSTRACT**This invention provides the use of *Botulinum* toxin (BTX) to cause paralysis of a depressor anguli oris (DAO) musculature in a patient to alleviate downturn at corners of the patient's mouth.**4 Claims, 2 Drawing Sheets**